IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. HEC PHARM CO., LTD. and HEC PHARM USA INC., Defendants.	C.A. 20-133-GBW (Consolidated)

MEMORANDUM OPINION

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April 6, 2023
Wilmington, Delaware

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

In this Hatch-Waxman Act action filed by Plaintiff Novartis Pharmaceuticals Corporation ("Novartis") against Defendants HEC Pharm Co., Ltd. and HEC Pharm USA Inc. (together, "HEC"), Novartis alleges infringement of U.S. Patent No. 10,543,179 ("the '179 patent"). The '179 patent relates to the treatment of relapsing-remitting multiple sclerosis ("RRMS"). Before the Court is the issue of claim construction of multiple terms in this patent. The Court has considered the parties' joint claim construction brief, related submissions, and argument at the claim construction hearing (the "Hearing"). *See* D.I. 152, 195, 196, 197, 220.

I. LEGAL STANDARDS

A. Claim Construction

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted); *see also Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989) ("A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention"). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d at 1324. The Court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.* The ultimate question of the proper construction of a patent is a question of law, although subsidiary fact-finding is sometimes necessary. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (quoting *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996)).

"The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history." *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir.

2012) (citing *Phillips*, 415 F.3d at 1312–13). A person of ordinary skill in the art "is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at at 1313.

"When construing claim terms, the court first looks to, and primarily rely on, the intrinsic evidence, including the claims themselves, the specification, and the prosecution history of the patent, which is usually dispositive." *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1276 (Fed. Cir. 2013). "Other claims of the patent in question, both asserted and unasserted, can . . . be valuable" in discerning the meaning of a disputed claim term because "claim terms are normally used consistently throughout the patent," and so, "the usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Phillips*, 415 F.3d at 1314. In addition, "[d]ifferences among claims can also be a useful guide[.]" *Id.* For example, "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15.

In addition to the claim, the Court should analyze the specification, which "is always highly relevant to the claim construction analysis ... [as] it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. "Even when the specification describes only a single embodiment, [however,] the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372

(Fed. Cir. 2014) (internal quotation marks omitted) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)). And, the specification "is not a substitute for, nor can it be used to rewrite, the chosen claim language." *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

The Court "should also consider the patent's prosecution history, if it is in evidence." *Markman*, 52 F.3d at 980. The prosecution history "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution[.]" *Phillips*, 415 F.3d at 1317.

In some cases, the Court "will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. Overall, while extrinsic evidence may be useful, it is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Phillips*, 415 F.3d at 1317 (internal quotation marks and citations omitted).

II. AGREED-UPON TERMS

The parties agreed upon the construction of the following terms:

Claim Term	Agreed-Upon Construction
"testing said patient for a history of infection caused by varicella zoster virus" (claim 1)	Plain and ordinary meaning: Checking said patient for a history or evidence of prior infection or vaccination
"thereby limiting the risk of infection caused by varicella zoster virus." (claim 1)	Plain and ordinary meaning: This phrase is a non-limiting statement of intended results from the claimed method.

The Court will adopt these agreed-upon constructions.

III. DISPUTED TERMS

A. Preamble: "A method for treating relapsing remitting multiple sclerosis in a patient in need thereof"

Claim Term	Plaintiff's Construction	Defendants' Construction	The Court's Construction
Preamble: "A method for treating relapsing remitting multiple sclerosis in a patient in need thereof," (claim 1)	The preamble is a limiting statement of purpose.	Limiting statement of purpose that does not require efficacy.	The preamble is a limiting statement of purpose.

The parties agree that the preamble is a limiting statement of purpose and does not require actual efficacy. D.I. 197 at 32-33, Tr. 10:4-5. Novartis explains that the preamble, in describing the claimed invention's purpose, contemplates an "efficacious purpose." Tr. 10:6-8; 14-16 ("A limiting statement of purpose that does require a belief in efficacy, but does not require an efficacious result"). HEC argues that Novartis' "efficacious purpose" disguises an additional limitation requiring "a mental state or intent of efficacy." Tr. 18:4-6.

Claim 1 of the '179 patent recites:

> 1. A method for treating relapsing remitting multiple sclerosis in a patient in need thereof, the method comprising:
>
> (a) identifying a patient at risk of contracting infection caused by varicella zoster virus by testing said patient for a history of infection caused by varicella zoster virus,
>
> (b) vaccinating the patient at risk of contracting infection caused by varicella zoster virus, and
>
> (c) administering orally fingolimod or a pharmaceutically acceptable salt thereof to said patient at a daily dosage of 0.5 mg, thereby limiting the risk of infection caused by varicella zoster virus.

'197 patent at cl. 1. The language of the preamble ("A method for treating relapsing remitting multiple sclerosis in a patient in need thereof") contemplates an efficacious purpose. Specifically, "treating" a patient "in need thereof" suggests that the purpose of the claimed method is therapeutically effective treatments rather than simply administering fingolimod without intending efficacy.

The efficacious purpose set forth in the claims is mirrored in the intrinsic record. The specification notes that that "there is a significant unmet need for effective new therapies in MS, which limit or reduce the possible adverse events or side effects." '179 patent at 1:31–34. The inventors discovered "a dosing regimen and a method of controlling, reducing, or abolishing the possible adverse events associated with treating a patient suffering from an inflammatory or autoimmune disease or disorder with a S1P receptor modulator or agonist, comprising administering to said patient a therapeutically effective amount of said S1P receptor modulator or agonist[.]" *Id.* at 8:1–7; *see also id.* at Abstract; *id.* at 1:1–3:35, *id.* at 7:33–8:47, *id.* at 10:47–63. During prosecution, the inventors contemplated efficacy, distinguishing a prior art reference by explaining it does not disclose that "0.5 mg is *effective in treating* multiple sclerosis." D.I. 196-1 at Appx1759; *see also id.* at Appx1760; *id.* at Appx1606 at ¶ 18.

HEC contends that its proposed construction excluding efficacy provides "scope-clarifying language" consistent with Judge Stark's construction of U.S. Patent No. 9,187,405 ("the '405 patent") in *Novartis Pharmaceuticals Corporation v. Accord Healthcare Inc.*, C.A. No. 18-1043-LPS, an action involving both Novartis and HEC. D.I. 197 at 32. There, Judge Stark construed certain claim preambles in the '405 patent reciting, *inter alia*, "A method for treating relapsing-remitting multiple sclerosis in a subject in need thereof, comprising . . ." as a "limiting statement of purpose." C.A. No. 18-1043-LPS, D.I. 561 at 5. But HEC takes Judge Stark's construction one

step too far. Although Judge Stark rejected Novartis' argument that the claims "require an actual effect," *id.* at 8-9 ("The Court agrees with Defendants and is not persuaded that anything in the claims, specification, or prosecution history warrant reading into the claims an efficacy limitation."), he nevertheless recognized that "the general purpose of the invention is to achieve a safe and effective manner of treating MS," *id.* at 9. Here, by specifically excluding efficacy, HEC's construction would import a negative limitation into the preamble untethered from the intrinsic record, and would undermine the general purpose of the invention of the '179 patent: to achieve a safe and effective manner of treating multiple sclerosis, or an efficacious purpose. Accordingly, the Court construes the preamble "A method for treating relapsing remitting multiple sclerosis in a patient in need thereof" as a limiting statement of purpose.

B. "a patient"

Claim Term	Plaintiff's Construction	Defendants' Construction	The Court's Construction
Novartis: "a patient" HEC: "a/the/said patient" (claim 1)	Plain and ordinary meaning: Any person under the care of one or more medical professionals	Plain and ordinary meaning: A patient diagnosed with RRMS that is not presently taking a daily dose of 0.5 mg fingolimod a pharmaceutically acceptable salt form of fingolimod	"a patient" means "a RRMS patient"

During the Hearing, while the parties agreed that a "patient" can be construed as "an RRMS patient," Tr. 24:17-22; 25:19-20, HEC maintains that the term needs further construction to specify that such RRMS patient is not presently taking a daily dose of 0.5 mg fingolimod. Tr. 26:6-7; 29:7-8.

Starting with the claims, the disputed "patient" terms appear in claim 1 of the '179 patent, which recites:

> 1. A method for treating relapsing remitting multiple sclerosis in **a patient** in need thereof, the method comprising:
> (a) identifying **a patient** at risk of contracting infection caused by varicella zoster virus by testing **said patient** for a history of infection caused by varicella zoster virus,
> (b) vaccinating **the patient** at risk of contracting infection caused by varicella zoster virus, and
> (c) administering orally fingolimod or a pharmaceutically acceptable salt thereof to **said patient** at a daily dosage of 0.5 mg, thereby limiting the risk of infection caused by varicella zoster virus.

'197 patent at cl. 1 (emphases added). The claim language, on its face, does not limit the "patient" to someone who is "not presently taking" a daily dose of 0.5 mg fingolimod. Neither is the sequential performance of steps (a), (b), and (c) contingent on whether a patient is presently taking a daily dose of 0.5 mg fingolimod.

Turning to the specification, it states that "the present invention relates to testing a patient for a history of infection and vaccinating the patient prior to administration of fingolimod or a pharmaceutically acceptable salt thereof at a daily dosage of 0.5 mg." '179 patent at Abstract; *see also id.* at 8:38–46, 10:59–63. These patients are not limited to individuals "not presently taking" a daily dose of 0.5 mg fingolimod.

HEC argues that the inventors acted as their own lexicographers, pointing to two definitions in the specification where the inventors distinguished between "a patient treated with fingolimod" and "a patient in need of prescribing fingolimod." D.I. 197 at 37-38; '179 patent at 5:31-36 ("As herein defined, a patient treated with fingolimod (FTY720) refers to a patient receiving fingolimod (FTY720), a phosphate derivative thereof (i.e. fingolimod-phosphate) or a pharmaceutically acceptable salt thereof, for treating an inflammatory or autoimmune disease or

disorder according to the invention, e.g. MS, e.g. RRMS."); *id.* at 5:37-40 ("As herein defined, a patient in need of prescribing fingolimod refers to a patient suffering from an inflammatory or autoimmune disease or disorder according to the invention, e.g. a MS patient."). Although these definitions support the Court's construction that a "patient" be a "RRMS patient," nowhere do these definitions suggest, as HEC urges, that a "patient" must not be presently taking a daily dose of 0.5 mg fingolimod. Rather, the specification teaches that the claimed method applies to both patient populations—that is, to those not presently taking fingolimod, but also those who may have received MS treatment in the past. *Id.* at 5:41-49 ("Patients treated with fingolimod (FTY720) and the patients in need of prescribing fingolimod may be patients who have never received treatment for an inflammatory or autoimmune disease or disorder, such as patients who have never received a treatment for treating or preventing MS, as well as patients who previously received one or more treatment for an inflammatory or autoimmune disease or disorder, for example who previously received one or more treatment for MS.").

These statements are in accord with other statements in the specification describing the monitoring of patients for possible adverse events before and during fingolimod administration. '179 patent at 7:34–67. In one embodiment, the specification describes monitoring the patient and "optionally interrupting" the fingolimod administration to, for example, administer "a second drug" to "mitigate[] . . . possible adverse events." *Id.* at 6:43–56. Thus, the specification does not exclude patients who may need to interrupt their fingolimod treatment so as to receive a varicella zoster virus vaccination to limit the risk of an infection.

Turning to the prosecution history, HEC argues that, because the applicant referenced the claimed method as a "proactive" form of infection prevention "prior to administering fingolimod", then the "foregoing screening and vaccination clearly contemplate a patient with RRMS that has

yet to receive fingolimod." D.I. 197 at 38-39. In a submission to the USPTO, the Applicant "submits that [prior art reference] does not teach the skilled artisan to practice proactive infection prevention methods prior to administering fingolimod, such as serological testing and, if indicated, vaccination, as claimed herein, much less teach proactive prevention measures for VZV specifically." D.I. 196-1 at Appx1515. But that submission does not compel a finding that a patient in the claimed step (a) must be one not presently taking fingolimod.[1]

In sum, the Court will construe "a patient" to be "a RRMS patient" consistent with the parties' agreement. Tr. 24:17-22; 25:19-20. The intrinsic record does not countenance limiting a "RRMS patient" to one not presently taking a daily dose of 0.5 mg fingolimod or a pharmaceutically acceptable salt form of fingolimod.

C. Steps of "identifying," "vaccinating" and "administering"

Claim Term	Plaintiff's Construction	Defendants' Construction	The Court's Construction
Steps of "identifying," "vaccinating" and "administering" (claim 1)	Plain and ordinary meaning: Steps (a), (b), and (c) must be performed sequentially	Steps must be performed in order and for the purpose of treating RRMS with fingolimod	Steps (a), (b), and (c) must be performed sequentially and for the purpose of treating RRMS

The parties agree that steps (a), (b), and (c) must be performed sequentially or "in order." D.I. 197 at 56, 57. HEC seeks to clarify that the steps be performed sequentially with two additional requirements: "for the purpose of treating RRMS with fingolimod." *Id.* at 57.

[1] HEC neither argues prosecution history disclaimer nor addresses the "clear and unmistakable" standard the Court uses to find disclaimer. *In re Lockwood*, 679 F. App'x 1021, 1027 (Fed. Cir. 2017); *see generally* D.I. 197 at 35-41.

The preamble to Claim 1, which this Court has construed *supra* as a limiting statement of purpose, recites, "A method for treating relapsing remitting multiple sclerosis in a patient in need thereof, the method comprising . . . " '179 patent at cl. 1. Explaining that each step of the method must be performed "for the purpose of treating RRMS" is consistent with the preamble, albeit arguably redundant, as the preamble already requires the claimed method to be performed for the purpose of treating RRMS in a patient in need thereof.

As HEC notes, if the parties disputed redundancy alone, the Court would have no claim construction dispute to resolve. Tr. 34:1-14 ("If we agree that each step of the method has to be performed for the purpose of treating an RRMS patient, then this is -- truly is two ships passing in the sea and there isn't a dispute."). Indeed, in view of the preamble, Novartis initially rejected HEC's addition as "redundant." D.I. 197 at 56 ("The addition is redundant to the claims' preambles, and thus would rendered [sic] them 'mere surplusage' which would be improper."); *id.* at 61 ("As the preamble gives life and vitality to the claim, the entire claim method must be performed with a purpose of treating RRMS in a patient in need thereof. There is no reason to import the treatment purpose into the body of the claim."). However, during the Hearing, Novartis argued something different, contending that HEC's additional language would be "imprecise" because each step may be accomplished for a different purpose. Tr. 36:16-17; 36:23-37:2 ("It is debatable, and I don't think the parties even engaged on this debate, whether the step of identifying is for the purpose of treating RRMS. It may be for the purpose of just identifying whether or not a patient is at risk of infection."); 38:7-11 ("where Step A has 'a patient,' Step B has 'the patient,' and Step C has 'said patient,' that is an indicator that each of these steps, you know, have a different

referral to the patient and, therefore, may not have overall an identical purpose.").[2] Thus, Novartis' shifting views reveal a dispute over claim scope such that the Court must construe this term beyond the parties' agreement that the steps be performed sequentially. *See 02 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008) ("When the parties raise an actual dispute regarding the proper scope of the[ ] claims, the court, not the jury, must resolve that dispute."). Accordingly, consistent with the intrinsic record, the Court concludes steps (a), (b), and (c) must be performed sequentially and for the purpose of treating RRMS.

The Court declines to adopt HEC's additional requirement that the sequential steps must be performed for the purpose of treating RRMS "with fingolimod." First, HEC's "with fingolimod" limitation is overly narrow. The steps of claim 1 recite:

> (a) identifying a patient at risk of contracting infection caused by varicella zoster virus by testing said patient for a history of infection caused by varicella zoster virus,
> (b) vaccinating the patient at risk of contracting infection caused by varicella zoster virus, and
> (c) administering orally fingolimod or a pharmaceutically acceptable salt thereof to said patient at a daily dosage of 0.5 mg, thereby limiting the risk of infection caused by varicella zoster virus.

'179 patent at cl. 1. As Novartis explains, to add to each step the requirement that a patient be identified, vaccinated and administered "for the purpose of treating RRMS with fingolimod" appears to require physicians to have already selected fingolimod to treat RRMS patients even

[2] Because Novartis' new position at the Hearing diverts from argument made in the Joint Claim Construction Brief, the Court declines to consider it. "In this district, a Markman hearing is not the time to raise a new claim construction argument." *CoolTVNetwork.com, Inc. v. Blackboard Inc.*, C.A. No. 19-291-LPS-JLH, 2020 WL 6536960, at *5 (D. Del. Nov. 6, 2020), *report and recommendation adopted*, C.A. No. 19-291-LPS-JLH, 2021 WL 2010579 (D. Del. May 20, 2021) (finding no error or abuse of discretion in Court's determination that "new arguments made for the first time at the claim construction hearing were untimely and waived").

before these treatment steps are performed. But on its face, the claim language does not exclude a method where a physician may be contemplating different treatment options (including fingolimod) for a RRMS patient while identifying a RRMS patient who is at risk of contracting varicella zoster virus infection and vaccinating such patient.[3] Second, adding "with fingolimod" to each step is confusing and incomplete in view of step (c), which contemplates administering fingolimod "or a pharmaceutically acceptable salt thereof." Third, while HEC appears to make a prosecution history disclaimer argument, explaining that "Novartis cannot now claim what it had to give up during prosecution" by citing a series of amendments and rejections, D.I. 197 at 57-60, HEC does not explain how Novartis clearly and unmistakably disavowed claim scope.[4]

In sum, the Court will construe "steps of 'identifying,' 'vaccinating' and 'administering'" as "[s]teps (a), (b), and (c) must be performed sequentially and for the purpose of treating RRMS."

IV. CONCLUSION

The Court will adopt the parties' agreed-upon constructions and construe the disputed claim terms as described above. The Court will issue an Order consistent with this Memorandum Opinion.

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[3] In response, HEC contends this example "is not the proper scope of the claim" but otherwise does not explain why Novartis' example does not render the "with fingolimod" limitation overly narrowing.

[4] Indeed, HEC cites to no authority on prosecution history disclaimer whatsoever. *See also supra* n. 2.